Canadian Agency for Drugs and Technologies in Health

Agence canadienne des médicaments et des technologies de la santé

OPTIMAL THERAPY REPORT

COMPUS

Physician Self-Audit Tool

September 2007

Supporting Informed Decisions

À l'appui des décisions éclairées

The statements, conclusions and views expressed herein do not necessarily represent the view of Health Canada or any Provincial or Territorial Government. Made possible through funding from Health Canada.

INTRODUCTION

The Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) self-audit tool is intended as a template and may be customized to suit the requirements of the distributor (provincial jurisdictions or continuing education providers, for example). The information collected enables the distributor of this tool to share COMPUS evidence-based information on proton pump inhibitors (PPIs), as well as acquire feedback on individual prescriber practices. This tool is not intended for physicians or prescribers to utilize on an individual basis.

The Canadian Agency for Drugs and Technologies in Health (CADTH), through its COMPUS program developed a physician self-audit tool as one of a range of tools to support the project on PPIs. Participation in this clinical self-audit will give prescribers the opportunity to optimize their PPI prescribing practices by reviewing their prescribing and use of PPIs for initial therapy, within their own clinical settings.

1 REVIEW OF PROTON PUMP INHIBITOR (PPI) PRESCRIBING

1.1 Prescriber Self-Audit Tool

a. Goals

To review the optimal use and prescribing of PPIs for initial therapy

b. How to participate

1.2 Phase 1 of the Clinical Audit Cycle

a. Select Patients

Select 10 patients ***retrospectively*** using paper or electronic medical records in whom you initiated PPI therapy for the first time.

b. Inform Patients

- Patients must be informed that de-identified information from their medical records may be used for clinical audits.
- Obtain patients' consent.

c. Record Patient Data – first data collection

Use the Patient Record Form to form a record of the patients included in the clinical audit.

d. Complete a clinical audit form for each patient.

e. Submit the clinical audit forms to:

Insert address here

f. Receive Results of Phase 1

- Review and reflect upon feedback on your individual results
- Review "Three Questions to Ask When Starting a Proton Pump Inhibitor (PPI)" newsletter and other attached information.

1.3 Phase 2 of the Clinical Audit cycle

a. Select Patients

Prospectively identify 10 patients who you are starting on a PPI for the first time.

b. Inform patients and record patient data (as above)

c. Complete a clinical audit form for each patient

d. Submit the clinical audit forms to:

Insert address here

e. Receive Results of Phase 2

Review and reflect upon feedback on your individual results and note differences in results from the retrospectively and prospectively identified patient groups

2 COMPUS OPTIMAL THERAPY NEWSLETTER

Canadian Agency for Drugs and Technologies in Health

COMPUS Optimal Therapy Newsletter: Proton Pump Inhibitors

Three Questions

Which PPI Should I Choose?

At What Dose Should I Start?

What Won't A PPI Treat?

The Canadian Agency for Drugs and Technologies in Health recognizes the importance of these questions to physicians and the COMPUS Expert Review Panel has carefully reviewed the evidence to offer some practical guidance to the prescribing and use of PPIs.

COMPUS: Canadian Optimal Medication Prescribing and Utilization Service

April 2007

Three Questions to Ask When Starting a Proton Pump Inhibitor (PPI)

1 Which PPI Should I Choose?

You've decided to prescribe a PPI for your patient. You want what is best for your patient – both clinically and economically. You want the best clinical outcome possible but you don't want your patient or the health-care system to pay more for that outcome than is necessary. With all of that in mind, which PPI should you choose?

Bottom Line:

There are no clinically important differences among equivalently-dosed PPIs in the treatment of most acid-related GI conditions.

PPI Pharmacology:

PPIs suppress gastric acid by irreversibly inhibiting the H^+/K^+-ATPase or the "proton pump" that secretes acid into the lumen of the stomach.[1] Since all five of the PPIs currently on the Canadian market have the same mechanism of action, it is expected that all would produce similar results at equivalent doses. Due to the irreversible binding of PPIs, subtle differences in pharmacokinetic properties may not significantly affect duration of action since new acid production requires regeneration of proton pumps.[1]

Evidence-based Support:

For **gastroesophageal reflux disease (GERD),**[2] including both endoscopy-negative reflux disease (ENRD) and esophagitis, no clinically important differences were found among standard doses of PPIs. The robust evidence supporting this conclusion includes six good-quality systematic reviews. While there are isolated exceptions, the majority of comparisons of PPIs for GERD showed no significant differences in short-term (four to eight week) and long-term (up to one year) studies.

For ***H. pylori* eradication,**[2] all PPIs have similar efficacy when used in triple-therapy regimens. Superiority of any one PPI was not suggested by any of the seven systematic reviews.

For **NSAID ulcer prophylaxis,**[2] indirect comparisons from a good quality systematic review and a direct comparison (omeprazole and pantoprazole) in a randomized control trial (RCT) found no clinically significant differences between the PPIs.

For **NSAID ulcer healing,**[2] the data is limited to a single good quality systematic review that included indirect comparisons of PPIs. These indirect comparisons suggest similar healing rates for the PPIs that have been studied (omeprazole and lansoprazole).

Limitations of the Evidence:

The evidence suggests that there are no clinically important differences among the various PPIs in the treatment of most acid-related GI conditions. This important message should not be clouded by isolated studies or comparisons between non-equivalent doses. However, the evidence is limited by the fact that direct comparisons have not been made for all agents in all indications. It should also be recognized that official indications for each brand of PPI may vary.

Implications for Clinical Practice:

With the evidence indicating that there are no clinically important differences among the PPIs for the treatment of common acid-related GI conditions, practitioners like you have the flexibility to choose lower-cost alternatives when prescribing PPIs, without compromising quality of care.

Price Comparison of Standard Once Daily-Dose PPIs

Generic Omeprazole 20 mg $1.25/day	Pariet® Rabeprazole 20 mg $1.30/day	Pantoloc® Pantoprazole 40 mg $1.90/day	Prevacid® Lansoprazole 30 mg $2.00/day	Nexium® Esomeprazole 20 mg $2.10/day	Losec® Omeprazole 20 mg $2.20/day

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The Canadian Agency for Drugs and Technologies in Health (CADTH) is a national body that provides Canada's federal, provincial and territorial health care decision makers with credible, impartial advice and evidence-based information about the effectiveness and efficiency of drugs and other health technologies.

600-865 Carling Ave
Ottawa, ON Canada K1S 5S8
Tel: (613) 226-2553
Fax: (613) 226-5392
web site: www.cadth.ca

We welcome your feedback.
Please send comments to:
compusfeedback@cadth.ca

References

[1] Richardson P, Hawkey CJ, Stack WA. Proton pump inhibitors: pharmacology and rationale for use in gastrointestinal disorders. *Drugs* 1998;56(3):307-35.

[2] Canadian Agency for Drugs and Technologies in Health. Evidence for PPI use in gastroesophageal reflux disease, dyspepsia and peptic ulcer disease: scientific report. *Optimal Therapy Report - COMPUS* 2007;1(2). Available: http://www.cadth.ca

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2 At what dose should I start?

Now that you've chosen which PPI to prescribe for your patient, you need to decide at what dose to initiate therapy. The evidence reviewed and compiled in the COMPUS Scientific Report on PPIs can help to guide this decision.

Bottom Line:

There is little evidence that more is better. Studies comparing standard doses of PPIs to high doses have **not** shown superiority of starting with the higher dose in the treatment of most acid-related GI conditions. Standard-dose therapy should be the initial therapy for most patients.

PPI Pharmacology:

PPIs inhibit gastric acid secretion in a dose-dependent manner.[1] However, most studies comparing standard- and high-dose PPIs have not shown significant differences in clinical outcomes.[2]

Evidence-based Support:

For **erosive esophagitis**,[2] it appears that high-dose PPIs are no better than standard-dose therapy in initial treatment. Six RCTs showed no significant differences in healing rates during initial treatment (four to eight weeks) between standard- and high-dose regimens. The majority of evidence suggests that standard-dose therapy is adequate for the initial treatment of erosive esophagitis.

Esomeprazole 40mg is indicated for erosive esophagitis. Some, but not all comparisons of esomeprazole 40mg daily with standard daily-doses of PPIs have shown benefit, although the clinical importance of these differences is not clear.[2]

For **NSAID-induced ulcer healing,**[2] standard- and high-dose omeprazole therapy were studied in two RCTs. High-dose therapy was not significantly better than standard-dose therapy in these trials.

Limitations of the Evidence:

There is good evidence to suggest that it isn't necessary to use high-dose PPI therapy as initial treatment for GERD and NSAID ulcer healing. The evidence is less clear on when it might be appropriate to consider doubling the standard dose. The COMPUS Scientific Report noted that evidence was lacking related to the use of high/double dose therapy for uninvestigated GERD with severe symptoms and for uninvestigated GERD/ENRD/erosive esophagitis patients who remain symptomatic on standard-dose therapy.[2] Higher-dose therapy may need to be considered in a small subset of patients who fail a reasonable (~ eight week) initial PPI trial at a standard dose.

Implications for Clinical Practice:

When initiating PPI therapy for your patients you can prescribe the standard daily dose knowing that the evidence shows this to be the best option.

3 What Won't a PPI treat?

There are times when the best decision is not to prescribe a PPI. The evidence presented in the COMPUS Scientific Report can help you decide when a PPI is not the best therapeutic option.

Bottom Line:

Current evidence would suggest PPIs are not efficacious in improving asthma, laryngeal symptoms or chronic cough that may be associated with GERD.

PPI Pharmacology:

PPIs are effective in reducing the production of acid, raising gastric pH and treating GI conditions that are related to acid production. Therapeutic benefits beyond this, although occasionally reported anecdotally, have not been shown in the available body of evidence.[2]

Evidence-based Support:

In the management of **asthma associated with GERD**,[2] a good quality systematic review suggested that treatment with PPIs did not improve FEV_1, morning peak expiratory flow, airway responsiveness or frequency of inhaler use.

For **laryngeal symptoms**,[2] evidence from a good quality systematic review suggested that PPIs performed no better than placebo in reducing symptoms such as throat clearing, sore throat, or hoarseness associated with reflux.

For **chronic cough**,[2] a good quality systematic review suggested there was no benefit of PPIs over placebo.

Implications for Clinical Practice:

Given that the evidence does not support the use of PPIs in certain clinical conditions such as asthma, laryngeal symptoms and chronic cough, you can choose not to initiate PPI therapy in these patients knowing this to be the best clinical option. Other therapy options can then be considered.

For full project details and intervention tools, please visit the CADTH web site:

www.cadth.ca

Medications associated with dyspepsia[1,2]	
NSAIDs/ASA/COX2 inhibitors	metformin (Glucophase®)
acarbose (Pradase®)	antibiotics / erythromycin
alcohol	orlistat (Xenical®)
alendronate (Fosamax®)	potassium
corticosteroids	theophylline
iron	

Herbs noted to have side effects that may be confused with dyspepsia	
Herb	**Side effect**
garlic	stomach burning, nausea
gingko	mild GI disturbances
saw palmetto	upset stomach
feverfew	GI disturbances
white willow	possible ADR similar to salicylates

Does patient have Alarm symptoms or is patient > 50 years?
VBAD
▪ vomiting ▪ bleeding/anemia ▪ abdominal mass / unexplained weight loss ▪ dysphagia ▪ age > 50 years
If YES • further investigation is warranted.

2.1 COMPUS Alternate Prescription Pad

Patient:_____

More than **1/4** of Canadians have symptoms caused by the acid in their stomach. Symptoms can include heartburn, indigestion, bloating and a feeling of fullness.

Whether or not you have been prescribed a medication, there are things you can do that may help reduce your symptoms.

☐ Avoid foods that worsen your symptoms, such as:
- coffee
- chocolate
- acidic foods (e.g., tomatoes, lemons)
- alcohol
- overly spicy or high-fat meals
- carbonated beverages

☐ Do not lie down for 2 to 3 hours after eating

☐ Do not wear tight-fitting clothing

☐ Stop or reduce the amount you smoke

☐ Elevate the head of your bed using blocks or books

☐ Eat smaller meals and chew food well

☐ Lose weight if appropriate

For full project information: **www.cadth.ca**

Disclaimer: This information is not a substitute for professional medical advice or care. CADTH is not liable for any damages resulting from the use or misuse of information contained in or implied by the information in this document.

Canadian Agency for Drugs and Technologies in Health

If your symptoms are mild or only occur once in a while, you may not need to take regular prescription medication.

You can treat your symptoms whenever they occur using medications available **without a prescription** at your local pharmacy. There are two types of products you can use:

Products That Neutralize Acid

Liquid or tablets (eg. Gaviscon®, Maalox®, Tums®)

➢ Works fast (5 to 15 minutes), lasts for 1 to 2 hours

➢ Pennies per dose, especially using store brand antacids

Products That Stop Acid Production

Zantac®, Pepcid® or generic ranitidine or famotidine

➢ Takes ~ 1 hour for effect, lasts for up to 12 hours

➢ Can cost as little as 25 cents per dose

Consult with your **Pharmacist** for the best option for you

If your symptoms don't go away within 2 weeks, or if they get worse: **Contact Your Doctor**

Doctor Signature:_____

Pharmacist Signature:_____

3 CLINICAL AUDIT FORM

3.1 Patient Details:

Is this the patient's first time taking a PPI? ☐ Yes (continue) ☐ No (not eligible for this audit)

Your patient code: _____ (do not use names)

Age range: ☐ < 55 years ☐ > 55 years

3.2 Primary Indication for Initiating PPI Therapy:

☐ uninvestigated GERD – mild
☐ uninvestigated GERD – moderate to severe
☐ confirmed GERD
☐ uninvestigated dyspepsia
☐ confirmed non-ulcer dyspepsia
☐ *H. pylori*-induced ulcer/ *H. pylori* eradication
☐ NSAID-induced ulcer prophylaxis
☐ NSAID-induced ulcer treatment
☐ erosive esophagitis (confirmed)
☐ Barrett's Esophagus
☐ asthma
☐ cough
☐ laryngeal symptoms
☐ uncertain diagnosis
☐ other: _____

Does the patient have alarm symptoms: vomiting, bleeding/anemia, abdominal mass/unexplained weight loss, dysphagia, age > 50 years?

☐ Yes
☐ No
☐ Uncertain

3.3 PPI Information:

Which PPI did you prescribe for initial therapy? At what daily dose?

☐	Generic Omeprazole	☐ 20 mg/day	☐ 40 mg/day	☐ Other:_____
☐	Rabeprazole (Pariet®)	☐ 20 mg/day	☐ 40 mg/day	☐ Other:_____
☐	Pantoprazole (Pantoloc®)	☐ 40 mg/day	☐ 80 mg/day	☐ Other:_____
☐	Lansoprazole (Prevacid®)	☐ 30 mg/day	☐ 60 mg/day	☐ Other:_____
☐	Esomeprazole (Nexium®)	☐ 20 mg/day	☐ 40 mg/day	☐ Other:_____
☐	Omeprazole (Losec®)	☐ 20 mg/day	☐ 40 mg/day	☐ Other:_____

What duration of initial PPI therapy did you prescribe?

- ☐ < 4 weeks
- ☐ 4-8 weeks
- ☐ > 8 weeks (please specify duration:_____)

Did you provide any repeats on the initial PPI prescription?

- ☐ Yes
- ☐ No
- ☐ Uncertain

3.4 Other Treatment Information:

Have you advised lifestyle modifications?

- ☐ Yes
- ☐ No
- ☐ Uncertain

Has the patient tried any other treatment(s) before the initial PPI therapy?

- ☐ antacids
- ☐ H2 antagonists (H2RAs)
- ☐ none
- ☐ not known

Is the patient using medications or herbs that may induce dyspepsia?

- ☐ Yes
- ☐ No
- ☐ Uncertain

4 REFERENCES

1. Thomson P. Dyspepsia and GERD. In: *Patient self-care: helping patients make therapeutic choices.* 1st ed. Ottawa: Canadian Pharmacists Association; 2002. p.256-63.
2. Bazaldua OV, Schneider FD. Evaluation and management of dyspepsia. *Am Fam Physician* 1999;60(6):1773-8. Available: http://www.aafp.org/afp/991015ap/1773.html (accessed 2005 Jul 18).